

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Earthjustice, Natural Resources Defense Council, Environmental Health Strategy Center and Toxic-Free Future on Proposed Inventory Notification Requirements under Section 8(b)(4)-(5) of the Amended Toxic Substances Control Act

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Safer Chemicals Healthy Families (SCHF), Earthjustice, Natural Resources Defense Council, Environmental Health Strategy Center and Toxic-free Future submit these comments on the Environmental Protection Agency's (EPA's) proposed rule to require retrospective notification of chemical substances manufactured or processed during the 10-year period ending on June 21, 2016 under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).¹

SCHF is a coalition of national, state and local organizations committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

The purpose of EPA's proposed rule is to enable it to identify "active" substances – those manufactured, imported or processed during the 10-year period preceding LCSA's enactment – so that it can designate Inventory-listed chemicals as "active" or "inactive." This Inventory "reset" process and related notification requirements are authorized by section 8(b)(4)(A) of the amended Toxic Substances Control Act (TSCA). In addition, EPA's proposal implements TSCA section 8(b)(5)(B), which requires persons intending to manufacture, import or process an inactive chemical to notify EPA in advance of commencing these activities so it can be added to the active substances portion of the Inventory.

The proposed rule will be useful in EPA's priority-setting activities and will provide the public with valuable information about the commercial status of Inventory-listed chemicals. SCHF generally supports EPA's proposal but seeks improvements in a number of areas that will enhance the informational value of notices filed under the rule. Our recommendations are presented below.

I. EPA Should Require Reporting by Persons Who Import Chemicals as Part of Articles When the Chemical is Released from the Article During End-Use and Serves a Separate Function

Congress limited notification under sections 8(b)(4) and (5) to chemicals "manufactured or processed for a non-exempt commercial purpose" during the ten years preceding enactment of the LCSA. The term "non-exempt commercial purpose" has historically been used by EPA in connection with the section 5 premanufacture notice (PMN) program. By including this term in the LCSA Inventory reset provisions, Congress intended that the scope of notification under these provisions would mirror the scope of PMN

¹ 82 Federal Register at 4255 (January 13, 2017).

requirements.² EPA's PMN regulations differentiate between new chemical uses subject to notification (which are produced for "non-exempt" purposes) and uses outside the scope of notification (which are produced for "exempt" purposes). Substances in the former category cannot be produced unless added to the Inventory through the PMN process; substances in the latter category may be produced without Inventory listing.

Section 710.27(a)(2) of the proposed rule would exempt from notification requirements the "import of a chemical substance as part of an article." EPA justifies this exemption in the preamble on the ground that –

"it would be incongruous to establish a more comprehensive reporting obligation for the import of active chemical substances under TSCA section 8(b)(5) (i.e. including import as part of an article), than would be applicable to the import of new chemical substances under TSCA section 5 (i.e. excluding import as part of an article)."³

While the PMN regulations exclude substances imported as part of articles from notification,⁴ EPA has recognized that different considerations are presented by substances that are released from articles during use and serve a purpose independent of the article itself and that such substances may be subject to PMN requirements.⁵ Since the new section 8(b) notification requirements are for the purpose of differentiating between active and inactive substances listed on the Inventory, we strongly urge EPA to include a limitation along these lines on the scope of the article exclusion in its Inventory reset regulations.

As EPA is well aware, substances in imported articles may be toxic and result in human or environmental exposure during use of the article. It is for this reason that Congress gave EPA the authority to develop Significant New Use Rules (SNURs) covering imported articles, and that EPA has in fact adopted such SNURs, requiring importers of articles containing chemicals of concern to notify EPA in advance of importation. Assuring that, when imported as part of articles, chemicals are listed on the Inventory as "active" where their release from the article can be anticipated would perform a similar function: if concerns about such a chemical's health or environmental effects are raised, EPA and the public would be aware that the chemical is in fact being imported into the US as part of an article and that actions to reduce exposure may be warranted.

EPA should revise section 710.27(a) so that substances contained in imported articles are subject to notification when they are released from the article during use and perform a separate end-use function.

II. EPA Should Require Notices of the Resumption of Manufacture or Processing to be Filed At Least 90 Days before These Activities are Commenced so that It is Able to Propose a SNUR Where Warranted

² As stated in the Senate report on S. 697, the Inventory reset provision "continues the practice under current TSCA to ensure that any substance that is exempt from the premanufacturing notification (PMN) process . . . is exempt from designation as active or inactive on the chemical inventory." S. Rep. No. 114-67 114th Congress 1st Session (2015) at 20.

³ 81 FR at 4279.

⁴ 40 CFR 720.22(b)(2).

⁵ See, e.g., USEPA, Questions & Answers for the New Chemicals Program, at 2-9.

TSCA section 8(b)(5)(B)(ii) requires any person “that intends to manufacture or process” an inactive chemical to notify EPA “before the date on which the substance is manufactured or processed.” By requiring advance notification, Congress apparently wanted to provide EPA an opportunity to take action to delay the resumption of manufacture or processing if it had concerns about the subject chemical. The best vehicle for such action would be a SNUR under TSCA section 5(a)(2). As EPA has interpreted this authority, discontinued uses can constitute “new uses” of a chemical for SNUR purposes. Thus, it would be straightforward for EPA to apply a SNUR to a chemical listed as “inactive” on the Inventory if there are health or environmental concerns about the chemical that make a resumption of commercial activities a “significant new use.” Such a SNUR would prohibit or limit manufacture or processing of the inactive substance pending receipt and review of a notification addressing the Agency’s concerns.

Section 710.30(b) of EPA’s proposal would require notification of the resumption of manufacture or processing of an inactive substance no later than 30 days before the date on which this activity occurs. Earlier notices would presumably be permitted, even on the date before the resumption of manufacturing and processing. This approach provides insufficient time for EPA to review a chemical and decide whether a SNUR is needed before the chemical is designated “active.” As a result, the purpose of providing advance notification would be undermined. We instead recommend requiring notification no less than 90 days, and no more than 120 days, before the anticipated start of manufacture or processing. This would ensure that the Agency has a meaningful opportunity to evaluate the chemical and make a judgement about the need for a SNUR.

In its preamble, EPA argues that a 30-day time period for forward-looking notification is necessary to minimize the risk that “business decisions, technical difficulties, and other unforeseen circumstances may delay a company’s plans to commercialize.”⁶ This is a concern, EPA says, because a delay could result in designating a chemical as “active” when in fact no manufacture or processing has yet occurred. Of course, this scenario is still possible where the notice is required within 30 days of the anticipated date of manufacture or processing. More importantly, EPA ignores the likely rationale for Congress’s decision to require notice based on “intent” to manufacture or process and in advance of when these activities are expected to occur. Since advance notification seems driven by the need to provide a window for EPA action, this should be the controlling consideration in establishing a notification timeline and, as discussed above, 30 days is simply inadequate from this perspective.

EPA can address its concern about commercialization delays by adding a requirement that the manufacturer or processor provide further notification once these activities have in fact begun (or a narrower requirement that the company notify EPA if its commercialization plans change and it is not proceeding with manufacture or processing as stated in the advance notice).

III. EPA Should Periodically Notify the Public of Substances Redesignated as “Active”

TSCA section 8(b)(7) requires that “EPA shall make available to the public . . . each chemical substance on the non-confidential . . . [Inventory], along with the designation . . . of the chemical substance as an active or inactive substance.” For chemicals whose identities have been claimed confidential, EPA must make available to the public generic identifying information, along with its status as active or inactive.

⁶ 82 FR at 4260.

EPA's proposal does not explain how it will carry out these obligations. For substances reported under section 8(b)(4)(A), we recommend that EPA publish an updated version of the Inventory which designates all listed substances as active or inactive. This should occur expeditiously, no later than 6 months after the completion of the notification process. For inactive substances designated as active based on notifications under section 8(b)(5)(B), since their changed status will not be immediately reflected on the Inventory, a different form of public notice is needed. To comply with TSCA section 8(b)(7), we urge EPA to publish a Federal Register notice, at least every 90 days, listing all substances designated active under the forward-looking reporting requirements within the preceding 90 days.

IV. EPA Should Require Reporting of the Site of Manufacture, Import and Processing on Forms A and B

Under section 710.29(b) of EPA's proposal, retrospective reports (Form As) must specify the type of commercial activity (manufacture, importation or processing) conducted on substances listed as active. Section 719.29(c) requires the same information in forward-looking reports. We support this requirement. An activity description should be simple to provide and is useful both for compliance and enforcement purposes and to promote basic understanding of the activity profile of the active chemical. Similar information was required in reporting for the Initial TSCA Inventory in 1979.

We urge EPA to further require reporting of the site(s) of manufacture, importation or processing. This will also enable EPA to verify whether notifications are in compliance with the inventory reset requirements and would also provide the public with useful information about the locations at which commercial activity involving the active substance is occurring.

V. CBI Claims for Chemical Identity in Retrospective Reports Should Be Substantiated at the Time Reports are Filed

Section 710.37(a) of EPA's proposed rule allows Form A submitters to seek continued CBI protection of the identities of chemicals reported as active if these chemicals are listed in the confidential portion of the existing TSCA Inventory. These CBI claims must be submitted as part of the Form A. If a preexisting CBI claim for chemical identity is not explicitly reasserted, the claim will lapse and the chemical will be moved to the public portion of the Inventory. The proposal allows submitters claiming CBI protection for chemical identity to substantiate the claim when the Form A is submitted, but does not allow such substantiation. Where substantiation is provided, it must respond to the specific questions in subsection (a)(1)(iii).

In our view, there are compelling reasons to require – not simply allow – CBI claims for the identities of active substances to be substantiated at the time the Form A is submitted. First, under section 710.37(b) of the proposal, CBI claims for other information in the Form A must not merely be asserted but substantiated when the Form is submitted. It would be most efficient for the submitter to justify CBI claims for chemical identity at the same time it is justifying the remaining CBI claims. Second, since submitters must make a conscious and informed decision whether to continue or waive CBI claims for chemical identity at the time the reporting form is completed, they will need to analyze the EPA criteria for CBI treatment and be able to demonstrate why these criteria are met. Thus, committing to writing the rationale for CBI protection in response to EPA's questions should require additional minimal time and effort. Indeed, if substantiation is not required at this point, submitters may reassert CBI claims for chemical identity without careful analysis, resulting in unsupported CBI claims that would have been weeded out if the company had answered EPA's substantiation questions.

According to the proposal preamble, EPA has not required upfront substantiation because TSCA section 8(b)(4)(C) provides for a separate rulemaking to establish a plan for reviewing CBI claims for the identities of chemicals reported as active under section 6(b)(4)(A). This plan must include a deadline for substantiating these CBI claims along with a process that provides for EPA to complete its evaluation of all such claims within 5 years.⁷

We believe that EPA can and should exercise its authority under sections 8(b)(4)(A) and 8(b)(4)(C) in an integrated manner and that, as part of the present rulemaking, it should determine that the appropriate deadline for requiring substantiation of CBI claims for chemical identity is when retrospective Form As are submitted. This would be consistent with EPA's obligation to set a timetable for requiring substantiation under section 8(b)(4)(D) while leaving the remainder of the review plan for future rulemaking.⁸ Such an approach would be more efficient for both EPA and reporting companies, because there would be only one substantiation package for CBI claims for Form A information. In addition, unwarranted CBI claims would be minimized and should EPA affirmatively wish to disclose chemical identity, it will have the substantiation in hand on which to base that decision rather than needing to request it from the submitter.

Conclusion

The undersigned organizations appreciate the opportunity to comment on EPA'S proposed notification rule under TSCA section 8(b) and look forward to working with EPA as it finalizes the rule.

Respectfully submitted,

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⁷ 81 FR at 4261.

⁸ Section 8(b)(4)(C) requires promulgation of the rule establishing the review plan "not later than 1 year" after EPA has compiled the initial list of active substances but does not bar earlier action by EPA, including as part of the notification rule promulgated under Section 8(b)(4)(A). It also doesn't bar EPA from developing the review plan in phases.